DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 12, 2014

MMP Medical Associates, LLC
Michail M. Pankratov, MD, PhD
Regulatory Consultant for BLT Industries, Ltd.
16 Appleton Street
Waltham, Massachusetts 02453

Re: K134040
Trade/Device Name: BTL-9000
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: August 8, 2014
Received: August 11, 2014

Dear Mr. Pankratov:

This letter corrects our substantially equivalent letter of September 10, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134040

Device Name
BTL-9000

Indications for Use *(Describe)*
The BTL-9000 device is a low level laser system that can be used for the non-invasive temporary reduction of waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.09.09 16:06:09 -04'00'

SECTION 5: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

I. General Information

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Summary Preparation Date: August 8, 2014

II. Device Information

Trade Name: BTL-9000

Common/Usual Name: Low level Laser System for Aesthetic Use

Classification: Class II

21 CFR 878.5400

Product Code: OLI

Classification Name: Low level Laser System for Aesthetic Use

Device Panel: General & Plastic Surgery

III. Predicate Devices

Device name	**BTL-9000**	**Strawberry & Cream Low Level Laser System**
Company name	**BTL Industries, Ltd.**	**Laser Lipo, Ltd.**
510(k) reference	K134040	K130341
Device description	Device consists of an electrically powered control unit using touchscreen interface. The system can operate using laser applicator that is connected to the control unit. A laser applicator is a device containing 4 cold laser red laser emitting diodes.	Device consists of an electrically powered control unit using touchscreen interface. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit. A paddle is a device containing 6 cold red laser emitting diodes.
Class	II	II
Product Code	OLI	OLI
Indications for use	The BTL-9000 device is a low level laser system that can be used for the non-invasive temporary reduction of waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.	Strawberry & Cream Low Level Laser System can be used for the non-invasive temporary reduction of waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.
Mechanism of Action	Disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.	Disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.
Power	200 mW per applicator	240 mW per paddle
Dimensions W x H x D	560 x 980 x 560 mm	275 x 185 x 315 mm
Configuration	Cabinet-mounted with wheels	Table top
Device classification	Class II, OLI, 878.5400	Class II, OLI, 878.5400

IV. Intended Use

The BTL-9000 device is a low level laser system that can be used for the non-invasive temporary reduction of waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

V. Device Description

The BTL-9000 consists of a control unit, connection lead to a BTL-9000 Laser Applicator and other accessories. (A full list of system contents is included in the operator's manual). The Laser Applicator is containing four cold red (660 nm) laser-emitting diodes and is designed to be placed on the skin. The output of the diode (four per applicator) is limited to 50mW ± 15% by a power limiting PCB from the central processing unit. The system can operate using 1 applicator that is connected to the control unit. The control unit is an electrically powered unit (100-240V, 50-60Hz auto-ranging). Once enabled it is controlled using a touchscreen interface. When the Laser Applicator is placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells and therefore reduced in size. The BTL-9000 is a stand-alone device which can be used together with other modalities which are not part of this submission.

VI. Materials

All materials used in the manufacture of the BTL-9000 have been demonstrated to meet strict design requirements, including requirements for durability and biocompatibility, and therefore suitable for use under the anticipated conditions of use associated with the device. There are no changes in materials that raise questions of safety or effectiveness.

VII. Testing

Based on the risk assessment of the modifications, bench testing and clinical testing were performed to ensure continued conformance to all product specifications, and equivalence to the predicate device.

The BTL-9000 module has been shown to conform to the applicable requirements of the following:

IEC 60601-2-22:1995 Ed.2
Medical Electrical Equipment - Part 2-22: Particular Requirements For The Safety Of Diagnostic And Therapeutic Laser Equipment.
IEC 60825-1:2007 Ed.2
Safety Of Laser Products - Part 1: Equipment Classification, And Requirements.
IEC 60601-1:1988 + A1:1991-11 +A2:1995
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2001 + A1:2004
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-4:2000 Consol. Ed. 1.1
Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
ISO 10993-5:2009
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ISO 14971:2007
Medical devices - Application of risk management to medical devices

For the BTL-9000 laser wavelength and output has been demonstrated (see SECTION 18) to be capable and substantially equivalent to the predicate device (Strawberry & Cream Low Level Laser System, Laser Lipo, Ltd.; K130341).

VIII. Clinical Testing

Clinical study: A double blind clinical study was conducted using 30 subjects: 15 subjects received BTL-9000 LLLT treatments, and other 15 subjects received placebo treatments. Subjects in both groups received 8 twice-a-week treatments. Their waist circumference and weight were evaluated at the baseline, at the end of the 8th treatment and at 30-day follow-up after the last treatment.
Results: No adverse events were experienced by any of the subjects. All subjects in BTL-9000 LLLT met the primary endpoint of a temporary waist circumference reduction (at the height of the iliac crest) of a minimum of 3 cm at 30-day follow up as compared to the baseline evaluation. The average recorded loss was 3.53 cm vs. -0.13 cm in Placebo group and was statistically significant. This procedure also produced, average 2.13 cm reduction in waist circumference immediately post-treatment vs. -0.1 in Placebo group that was also statistically significant. The reductions were also statistically significant within the treatment group: baseline vs. post-treatment, baseline vs. 30-day follow up, and post-treatment vs. 30-day follow up.

Table VIII-1. Subjects in Treatment Group – Mean Waist Circumference and Mean Change in Waist Circumference

		Waist Circumference (cm)			Change in Waist Circumference (cm)		
	Age	Pre-Tx	Post-Tx	30-day FU	Pre-Tx vs. Post-Tx	Pre-Tx vs. 30d FU	Post-Tx vs. 30d FU
Mean±SD	44.73± 11.39	91.37± 13.14	89.23± 12.95	87.83± 13.14	2.13± 0.61	3.53± 0.40	1.40± 0.60

Median (Min-Max)	43 (30-68)	89 (69-118)	87.5 (66-115)	85.5 (66.5-114.5)	2 (1–3)	3.5 (3.0 -4.5)	1.5 (0.5 –2.5)

Table VIII-2. Subjects in Placebo Group – Mean Waist Circumference and Mean Change in Waist Circumference

		Waist Circumference (cm)			**Change in Waist Circumference (cm)**		
	Age	**Pre-Tx**	**Post-Tx**	**30-day FU**	**Pre-Tx vs. Post-Tx**	**Pre-Tx vs. 30d FU**	**Post-Tx vs. 30d FU**
Mean±SD	45.13± 13.24	92.5± 9.69	92.6± 9.49	92.63± 9.58	-0.1± 0.69	-0.13± 0.61	-0.03± 0.44
Median (Min- Max)	46 (27-65)	91.5 (74.5-107)	91.5 (75-107.5)	91.5 (75-107.5)	0 (-1–1.5)	-0.5 (-0.5-1.5)	0 (-1 – 0.5)

Conclusions: The 8 twice-a-week treatments with BTL-9000 at maximum power produce reliable reduction in waist circumference. There was statistically significant difference between the Treatment and Placebo Groups in change in waist circumference from pre- to post-treatment, from pre-treatment to 30-day follow up, from port-treatment to 30-day follow up.

IX. Substantial Equivalence

The BTL-9000 is substantially equivalent to its predicate device when used according to its intended use. This is based on the information provided in this **510(k)** Premarket Notification which demonstrates that the BTL-9000 shares the same technological characteristics, mechanism of action, intended use and physical properties when compared to its predicates.

X. Conclusion

Based on similar intended use, technological characteristics, and technical and clinical performance characteristics, the BTL-9000 is substantially equivalent to its respective predicate device.